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Relationship of Modic changes, Disc Herniation Morphology and Axial Location to Outcomes in Symptomatic Cervical Disc Herniation Patients Treated with High Velocity, Low Amplitude Spinal Manipulation: A prospective study

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Abstract

Objectives

To evaluate whether cervical disc herniation (CDH) location, morphology or Modic changes are related to treatment outcomes.

Methods

MRI and outcome data from 44 CDH patients treated with SMT were evaluated. MRI scans were assessed for CDH axial location, morphology, and Modic changes.
Pain (0-10 for neck and arm) and Neck Disability Index (NDI) data were collected at baseline, 2 weeks, 1, 3, 6 months and 1 year. The Patient's Global Impression of Change data was collected at all time points and dichotomized into 'improved' yes/no.
Fischer's exact test compared the proportion 'improved' with MRI abnormalities.
NRS and NDI scores were compared at baseline and change scores at all time points using the t-test or Mann Whitney U-test with MRI abnormalities.

Results

Modic positive patients had higher baseline NDI scores ($p = 0.02$). 77.8% of Modic positive and 53.3% of Modic negative patients reported improvement at 2 weeks ($p = 0.21$). 50% of Modic I and 83.3% of Modic II patients were improved at 2 weeks ($p = 0.07$). At 3 months and 1 year all patients with Modic changes were 'improved'. Modic positive patients had higher NRS and NDI change scores.
Patients with central herniations were more likely to 'improve' only at the 2 week time point ($p = 0.022$).

Conclusions

Although Modic positive patients had higher baseline NDI scores, the proportion of these patients 'improved' was higher for all time points up to 6 months. Modic I patients do worse than Modic II only at 2 weeks.

Introduction

After low back pain, neck pain is the second most common complaint that presents to a chiropractic practice.[1-3] A relatively common subgroup of neck pain is cervical radiculopathy (CR) with an annual incidence of about 80 cases per 100,000 people.[4] Patients with CR present with neck pain, arm pain in a dermatomal pattern as well as neurological deficits including motor weakness, decreased deep tendon reflexes or dermatomal sensory loss.[5,6] The nerve roots of C6 and C7 are the most frequently affected levels.[4]

Clinically, the best tests to diagnose CR are 1) the upper limb tension test A, 2) less than 60° of cervical rotation, 3) positive Spurling test and 4) pain relief with cervical distraction.[7] These tests seem to have the best diagnostic accuracy. If 3 out of the 4 are positive, there is a probability of 65% that CR is present, and with all 4 tests positive, the chance increases to 90%.[7] For further investigation, MRI is the most often used imaging modality to detect CR because it detects neural structures, such as cervical nerve roots, directly.[8] MRI has demonstrated a better accuracy in the prediction of cervical disc herniation (CDH) causing CR compared to other imaging modalities such as computer tomography (CT) or plain films.[9] In addition, MRI can also rule out the unusual case of pathology as a cause of CR such as intra- or extradural spinal tumors or epidural abscess.[5]

In unclear cases, for the differentiation of other neurological conditions that may imitate CR, electro-diagnostic studies have been shown to be very useful as a further investigation method.[8] Thus it is important to link the clinical findings with the findings on the MRI study. The reason is that degenerative disc changes including CDH are frequently seen in asymptomatic persons.[10-12]

The exact pathogenesis of CR is still not clear. Some of the causes of CR are degenerative changes like CDH, spondylotic spurring of the uncovertebral or facet joints or a combination of these, that lead to compression of the nerve root in the intervertebral foramen (IVF).[5] In addition to the mechanical compression, inflammatory changes in the nerve root and in the dorsal root ganglion seem to play an important role for the pain generation. Neurogenic chemical mediators of pain can be released by the neural cell bodies and non-neurogenic mediators of pain by the disc tissue.[13]

To further complicate matters, recent studies have shown that Modic Changes (MC) are commonly associated with disc herniations in both the lumbar and cervical spine.[14] MC are specific endplate signal changes in the spine categorized into three types: MC type I (bone marrow edema), II (fat), and III (subchondral bone sclerosis).[15] In the literature they are associated with non-specific spinal pain syndromes, especially the type I.[16,17] There are two main theories about the pathophysiology of MC, a biomechanical theory and an infection theory. The biomechanical theory explains the MC as a result of mechanical stress at the vertebral endplate.[18-20] Because disc degeneration is also a result of improper loading of the disc, the literature supports this theory with studies that show an increased incidence of Modic changes in patients with disc degeneration.[21,22] The infection theory implies that the edema in the vertebral endplate is caused by

pyogenic infection of the disc
and adjacent endplates. However controversy exists in the literature about this theory.[23-25]

For disc herniation patients it has been shown that patients with MC show a slower resorption of the discus hernia.[26] In addition, the literature often reports a poorer outcome of MC positive individuals with various treatments.[27-29] However, spinal manipulative therapy is not one of the treatments evaluated in MC positive patients.

The treatment of cervical radiculopathy can be divided into conservative and surgical treatment methods.[30.31] Surgical treatment options contain several different methods and are generally considered in the absence of success with conservative treatment.[32] The pool of conservative treatment methods for CR includes different manual and physical therapies as well as oral or invasive application of anti-inflammatory medication. Epidural or nerve root infiltration shows good evidence that many patients with CR benefit from this treatment in terms of short and long term outcome.[29,33,34]

The evidence for spinal manipulative therapy (SMT) as a treatment method for CDH with CR is sparse in the literature. Murphy et al studied 35 patients with CR that were treated conservatively with an individualized combination of high velocity, low amplitude (HVLA) manipulation, muscle energy techniques, neural mobilization techniques, traction treatment, non-steroidal anti-inflammatory medication, oral corticosteroids, epidural steroid injection and different types of rehabilitation exercises. They reported a mean self-rated improvement of 88% and a mean reduction in pain of 72% at 3 months after the initial treatment.[31] Although this study used cervical HVLA manipulation as the central part of their treatment, the other modalities were added individually. This means that the outcome cannot be related only to the HVLA manipulation. Peterson et al. looked at the effect of HVLA alone for the treatment of MRI confirmed cervical disc herniation patients with radiculopathy. They examined the effect of HVLA manipulation at the level of the symptomatic CDH combined with local ice application. At three months after the initial treatment the patients had a mean reduction in pain scores of 66%. In addition 93% of the acute (symptoms duration < 4 weeks) and 76% of the chronic (symptoms duration > 12 weeks) patients reported their global impression of change as better or much better.[35]

There is some research evidence supporting the use of HVLA SMT for patients with symptomatic cervical disc herniations but the importance of specific MRI findings relevant to the treatment outcomes has not been studied. Therefore the purposes of this study are 1) Compare the specific MRI CDH findings of location in the axial plane, morphology, CDH level and the presence/absence and type of Modic changes to treatment outcomes; 2) Examine the inter-rater reliability of using the accepted nomenclature for CDH as well as for MCs.

Methods

Ethics approval was obtained from the Hospital and Canton ethics committees before the start of the study (EK 21/2009).

Patients

Inclusion criteria

This is a retrospective analysis of the MRI scans from patients included in a previous prospective, cohort, outcome study about symptomatic CDH treated by spinal manipulative therapy (SMT) done by Peterson et al. in 2013.[35] The patients had been recruited from a single chiropractic practice in Zurich, Switzerland from January 2010 to April 2013. The subjects were between 24 and 66 years of age. Inclusion criteria had been the following: Neck pain and moderate to severe arm pain in a dermatomal pattern, sensory, motor or reflex alterations corresponding to the involved MRI-confirmed nerve root level. In addition at least one of the following clinical tests for radiculopathy had been required: (a) positive upper limb tension test, (b) positive cervical traction test, (c) positive Spurling test, (d) cervical rotation less than 60°. Those tests were considered by Wainner et al as the most reliable and accurate for the evaluation of CR.[7] In addition an MRI proven CDH at the corresponding level was required.

Exclusion criteria

Initial exclusion criteria for the first study done in 2013 were contraindication to spinal manipulative therapy such as tumors, infections, inflammatory arthropathies, acute fractures, Paget`s disease, anti-coagulation therapy, cervical spondylotic myelopathy, known unstable congenital anomalies and severe osteoporosis.[35] Also patients with previous spinal surgery, a history of strokes, signs of cervical spondylotic myelopathy, spinal stenosis or pregnancy had been excluded. In addition to the above mentioned, patients whose MRIs were no longer available to analyse were excluded from the current study.

Baseline Data and Outcome measures

In the study from 2013 patients first completed a demographic information questionnaire and a baseline questionnaire, including the numerical rating scale (NRS) for pain and the neck disability index (NDI) as secondary outcome measurements.[35] The NRS for pain is an 11-point rating scale with 0 being no pain and 10 being the worst pain imaginable. Patients completed separate NRS scales for neck and arm pain. It is an accurate, reliable, repeatable and sensitive measurement for pain intensity assessment.[36] In addition, the NDI was also included. It is a commonly used questionnaire for measuring self-rated disability due to pain and it has been shown to be valid and reliable.[37] At 2 weeks, 1 month, 3 months, 6 months and 1 year after the initial consultation, a trained research assistant, that was independent from the treating practice, interviewed all patients by telephone to collect the NDI, both NRS`s and the Patient's Global Impression of Change (PGIC) data. The PGIC is considered as the primary outcome measurement for this study. It consists of a 7 point verbal scale containing the following responses: much worse, worse, slightly worse, no change, slightly better, better and much better. Only the responses 'much better' and 'better' were considered as clinically relevant' improvement', as it was determined in previous studies.[38]

Treatment procedure
The patients had been treated by a standardized single HVLA cervical SMT at the level of the symptomatic CDH (figure 1). Treatments were repeated 3 to 5 times per week during the first 2 to 4 weeks and 1-3 times per week afterwards until the patients were asymptomatic. These treatments had been administered by 3 different Doctors of Chiropractic (DC). All had been working in the same practice for several years. They had between 6 and 30 years of clinical experience. Because the senior DC educated the younger chiropractors during their post-graduate residency programs, the SMT method can be seen as standardized. Patients had been allowed to take pain medications if needed, but this was not evaluated in the study. If patients wanted to have additional treatment modalities such as surgery or nerve root infiltration, these options were discussed with the chiropractor. If one of these treatments had been administered, the patient would have been deleted from the study. This did not happen in any of the cases.

MRI analysis
All MRIs of the included patients were analyzed for MCs and intervertebral disc herniation. The MRIs were read independently by two chiropractors in the government accredited post-graduate programme (residents) for the reliability part of this study and a professor with a special education in musculoskeletal imaging with 28 years of experience. A consensus reading amongst the 3 evaluators was then used for the outcome evaluations.

For MCs the type (MC I or II) and the spinal level in which they were present for each patient was assessed and recorded. All CDHs in the MRI studies of the included patients were evaluated and recorded according to the latest update on spinal disc nomenclature. Although the recommendations used were designed for the lumbar spine, the authors stated that these can be easily extrapolated to the cervical spine.[12]

The spinal level of the CDH was identified, the location category and the type classification. By location category the DH was labelled as central, paramedian/paracentral, foraminal or extraforaminal. Relating to the type of classification, these were labelled as disc bulge, disc protrusion, disc extrusion or disc sequestration as described by Fardon et al.[12] A disc bulge is described as a widening of more than 25% of the disc's circumference. A disc herniation is defined as a disc displacement that is less than 25% of its circumference. The difference between an extrusion and a protrusion is that in an extrusion the base of the disc herniation has a smaller diameter than the widest diameter of the disc herniation, whereas in a protrusion the base diameter is bigger than the widest diameter of the herniation (figure 2). Finally a sequester describes a part of the disc material that has lost its contact to the disc and floats freely in the spinal canal.[12]
Finally whether or not MCs and CDHs were at the same level was recorded.

Statistical analysis
Primary outcome statistics
The PGIC scale was dichotomized into 'improved' and 'not improved' patients as described above. The percentage of patients improved or not improved was calculated for all time points. Fischer's exact test was used to compare the proportion of patients 'improved' for the various categories of MRI abnormalities. P <

0.05 was considered statistically significant. (Unfortunately the number of patients with MC type I was small and did not reach the required minimum of 5 patients for 3 of the data collection time points required to perform the Chi-square test for this particular MRI finding. Only the time points of 3 months and 1 year met the minimum requirement.)

Secondary outcome statistics

To assess differences in NRS neck pain, NRS arm pain and NDI scores between MC positive and MC negative patients at each time point the Mann Whitney-U test was performed (non-parametric data). The change scores for NRS neck pain, NRS arm pain and NDI scores between baseline and all time points were calculated for the MC positive and MC negative groups separately (normally distributed data) and compared using the unpaired Student's t-test. The unpaired t-test was also used to compare differences in NRS neck pain change scores, NRS arm pain change scores and NDI change scores between MC type I and MC negative groups at each time point.

Inter-examiner reliability analysis

The Kappa reliability test and percentage calculation according to Landis & Koch 1977 were used to evaluate the inter-examiner reliability between the independent readings of the MRI by the main author and a co-author, both chiropractic residents in the post-graduate programme.[39] The Kappa test labels reliability in the following levels: poor (0 – 0.2), fair (0.21 – 0.40), moderate (0.41 – 0.60), substantial (0.61 – 0.80) and almost perfect (0.81 – 1.00).[39]

Kappa values were obtained for the following MRI findings: If MC were present or not, categorisation of MC, spinal level of MC, CDH level, location category of the CDH (central, paramedian, foraminal or extraforaminal), type classification of the CDH (bulge, protrusion, extrusion or sequester) and if MC and CDH were at the same spinal level or not.

Results

A total of 44 patients were available at baseline for the analysis. The mean age was 44.73 years with a standard deviation (SD) of 7.9. The sample size changed between the different time points, due to relatively narrow time frames allowed for the follow up telephone calls. Although for some patients some telephone calls were missing, they stayed in the study unless 3 consecutive telephone calls were missed. The mean age in patients with MC was 47.69 years (SD 8.9), the mean age in patients without MC was 43.35 years (SD 7.3) ($p = 0.099$). Like the total sample size, also the number of MC positive and MC negative patients fluctuated slightly between the different time points.

There were 51 cervical motion segments with CDH: 7 classified as bulge, 25 classified as protrusion, 19 classified as extrusion and no sequestrations.

At 2 weeks 56.3% of all patients showed a clinically significant improvement, this number increased gradually until reaching 100% at 1 year after start of treatment (table 1).

There were no significant differences in treatment outcomes for any of the data collection time points for MC spinal level, CDH spinal level, CDH type (i.e. morphology) classification and if MC and CDH are at the same level. CDH location in the axial plane classification showed that 77.8% of patients with central herniations reported 'improvement' at the 2 week time point compared to 44.4% of patients with paracentral herniations and 20.0% of patients with foraminal herniations ($p = 0.022$). However, no significant difference in the proportion of patients 'improved' at the other data collection time points was found.

Table 1 shows the number of patients with Modic changes and their types for the various data collection time points. In three cases T1-weighted MRI images were not available in order to classify Modic positive patients as to type I or II and were only assessed with the T2-weighted slices as Modic positive. In patients with MC (both type I and II), although not statistically significant, 77.8% reported clinically relevant improvement at 2 weeks, while 53.3% of patients without MC had clinically relevant improvement X^2 (1, N = 31) = .30, $p = 0.21$. With the exception of the 6 month time point for the MC positive patients, all patients in both MC positive and MC negative groups showed a gradual increase in the proportion of patients with clinically significant improvement until reaching 100% at 1 year after treatment. From 3 months after treatment all patients with MC type I and II reported clinically significant improvement.

Comparison of patients with MC and without MC in relation to NRS for neck pain, NRS for arm pain and NDI total score showed a statistically significant difference for NDI total score at baseline ($p = 0.04$) and a trend at 6 months ($p = 0.07$) after treatment (table 2) with Modic positive patients having higher change scores (i.e. more reduction in disability).

Differences in change scores for NRS neck pain, NRS arm pain as well as NDI total scores between MC positive and MC negative patients showed that for all time points except NRS arm pain at 6 months, the MC positive patients had higher change scores (i.e. more pain relief and higher reductions in disability). However this did not reach statistical significance (table 3). Similarly, when comparing the MC negative patients with MC I patients only, the MC I patients had higher NRS neck pain and arm pain change scores as well as higher NDI change scores at all time points. This also did not reach statistical significance however (table 4).

The interexaminer reliability analysis showed a range of reliability categories between fair and perfect (table 5). In particular the reliability for MC present or absent, MC category and MC and CDH at the same level revealed almost perfect to perfect Kappa results and also with high percent agreements. The lowest reliability was found in the CDH location and CDH level groups.

Discussion

In this prospective, cohort, outcome study with CDH patients treated with HVLA cervical manipulation by one of 3 chiropractors, the purpose was to evaluate the outcome differences in relation to the presence or absence of MCs as well as whether or not the morphology or axial location of the herniation were related to treatment outcomes. No other study has looked at this previously for the cervical spine. It is known from the literature that patients with MC are associated with more spinal pain, particularly patients with MC type I.[28,40,41] Consistent with this fact is that in this current study, CDH patients with MC reported significantly higher baseline disability scores on the NDI which is not surprising and consistent with the reported literature.[42] However, at all follow-up time-points, except for arm pain at 6 months, MC positive patients had higher NRS and NDI change scores, meaning that their levels of pain and disability reduction were higher than patients without MC. This was also found when MC type I was compared to no MC. The results did not reach statistical significance however, most likely due to the small sample size (underpowered). There were some follow-up time-points that almost reached statistical significance however, even with the small sample sizes (6 month NRS change score, 6 month NDI change score and 1 year NDI change score; all with $p < 0.10$) thus showing a trend for the MC positive patients to have better outcomes in spite of having more disability prior to treatment. These results were not expected as they are contrary to those published in the literature so far for other treatments.[27-29]

For non-specific low back pain there are current studies which stated that MCs are associated with back pain syndromes.[40,42] Also a systematic review in 2008 stated that MCs are associated with lumbar spine pain syndromes.[40] However, most studies do not specifically look at low back pain patients with lumbar disc herniations (LDH) and importantly few have evaluated responses to specific treatments.

A possible explanation, as to why SMT may help in patients with MCs is hypothesized below. It has been shown that most MCs show a natural progression, usually from MC type I to MC type II and may even disappear in some cases.[43,44] As MC type I has more association with pain syndromes, it has been shown that these pain syndromes may disappear gradually over time due to the natural progression of MCs.[17,42,44,45] The theory that MCs are caused by overloading and shear forces of the vertebral disc, that lead to an inflammatory state of these structures indicates that MCs can be an origin of spinal pain syndromes.[18] Spinal pain syndromes show an increased electromyographic (EMG) activity of paraspinal muscles, which can irritate the already inflamed joint even more.[46] If the above mentioned facts are linked with studies that show that SMT reduces paraspinal muscle activity, one can hypothesize that SMT may reduce pain in patients with MCs.[47] This can be seen as a pain reducing treatment during the natural history of MC or potentially SMT supports or even accelerates the progression of MC.

However, in a recent study by Annen et al., lumbar disc herniation patients with Modic type I changes who were treated with high velocity, low amplitude spinal manipulation showed a pattern of improvement and recurrence over time compared to patients with Modic type II and patients without Modic changes who improved and stabilized.[48] Thus it appears when comparing this current study on the cervical spine with the similar study on the lumbar spine that there is a difference between the cervical and lumbar spinal regions with respect to the influence of Modic changes on treatment outcomes. This highlights the importance of multiple data collection time points.

Currently, the response of patients with MC to different treatment methods remains unclear in the lumbar spinal region as well. A systematic review done by Jensen et al in 2008 found 6 good quality studies that measured outcomes of patients with MC for different treatments.[27] Two studies, one with intradiscal steroid injection and the other with fusion surgery as treatment methods, reported a favourable outcome for MC patients. Another study with intradiscal steroid injection and one with epidural steroid injection showed mixed results however. Exercise therapy and lumbar disc replacement showed negative outcomes in patients with MC. This review stated that there are too few studies on this topic to make a general opinion on how patients with MCs respond to various treatments.
Peterson et al examined the effect of lumbar nerve root infiltration in symptomatic MRI-confirmed LDH patients.[28] They found that LDH patients with MC had significantly higher pain levels and significantly less pain reduction 1 month after treatment compared with LDH patients without MC. A recently published study using the same protocol was done for CDH patients and the results were similar.[29]

To summarize, the results of this current study on cervical disc herniation patients indicating better treatment outcomes for CDH patients with MC are generally consistent with those reported for LDH patients, other than the fact that the CDH MC patients reported no relapses. However, it is in contrast to the overall results of other treatments in the literature so far. The other treatments studied are more passive treatments (injections, surgical fusion) compared to the active treatment of HVLA SMT and this may be one reason for the differences in outcomes.

This study did not find any association between the different types and axial plane locations of CDH and outcomes except at the 2 week data collection time point. A significantly higher proportion of patients with central disc herniations reported 'improvement' at this time point compared to patients with either paracentral or foraminal herniations. However, due to the large variety of different types and locations (central, paramedian, foraminal and extraforaminal for CDH location category; protrusion, extrusion and sequester for CDH type classification) very small sample sizes resulted for the different configurations. Studies with larger sample sizes need to be done to further investigate whether or not CDH configurations are related to positive or negative outcomes in CDH patients treated by cervical HVLA manipulation. However, these results are consistent with what was reported for the similar study evaluating lumbar disc herniation patients treated with HVLA SMT.[49] One interesting difference between this current study and the LDH study however, is that there were no cases of disc sequestration for the CDH patients, whereas disc sequestration was the second most common morphology in the LDH study.[49] Another study that examined treatment outcomes for cervical nerve root infiltration found that CDH patients with extrusions were more likely to end up in surgical treatment.[29]
It is also important to mention that none of the patients in this current study reported worsening of their condition. Cervical HVLA manipulation has been controversial with suggestions that it can lead to vertebral artery dissection and stroke.[50,51] However, in 2007 a prospective national survey done by Thiel et al studied almost 20,000 patients who were treated with cervical HVLA manipulation or mechanically assisted thrust.[52] There were no reports of serious adverse events, which were defined as symptoms with immediate onset after treatment and with persistent or significant disability. They reported frequently occurring minor adverse events such as fainting,

dizziness, light-headedness, headaches and numbness/tingling in the upper extremities. To investigate the controversy as to whether or not cervical HVLA manipulation is a risk factor for vertebral artery dissection, Cassidy et al, using a case-control research design on a huge sample size in Canada, could not find an additional risk of vertebrobasilar stroke after cervical spine manipulation by chiropractors compared to patients consulting medical doctors for the same symptoms.[53] They showed that in the population of Ontario, Canada during the period from 1993 to 2002 the incidence of vertebrobasilar stroke has approximately the same association with chiropractic and primary care visits. They indicated that these patients seek for care because of the prodromal symptoms of vertebrobasilar stroke like neck pain or headache.

The results for the interexaminer reliability of diagnosing and categorizing the MRI findings in this current study were almost perfect to perfect for MC present or absent, identifying MC type and if MC and CDH were at the same level. Two studies that examined interexaminer reliability for the lumbar spine also showed good agreement for MC.[54,55] A third study found moderate interexaminer agreement for MC.[56] For the cervical spine the interexaminer reliability for MC has been described as substantial.[29] In this current study substantial agreement was also achieved for identifying the level of MC. This is consistent with the above mentioned studies that support the good results for MC.

For CDH type classification and location category a moderate agreement was found and for CDH level a fair agreement resulted. A similar study done by Bensler et al also found a fair agreement for CDH location and a substantial agreement for CDH type classification.[29] One issue that arose during the consensus reading of the images was the distinction between paramedian and foraminal CDH. It was sometimes challenging to decide which of these categories to select because often the CDH had both foraminal and paramedian components. Another problem was the distinction between protrusion and extrusion in oblique slices, because the uncinate processes tapered the disc. The low agreement for CDH level may be explained by the fact that some patients had several levels with CDH and all disc herniations of a patient had to be rated identically by the two examiners to count as a positive match. In addition it has to be mentioned that the two examiners that performed the inter-examiner reliability part of this study were two young chiropractors with 6 months and 1.5 years of clinical postgraduate experience. However, both had received specific training in the diagnosis and categorization of these MRI findings.

Limitations

One of the main limitations of this study is the small sample size. This was especially problematic when it came to the analysis of subgroups. This was the case for all statistics including MC and for the statistics of the different disc herniation classifications. Thus this study was somewhat underpowered.

Another limitation was that other possible causes of radiculopathy that may be visible on MRI scans were not considered. These would include nerve root compression by hypertrophy of uncinated processes or facet joints. However, due to the relatively small sample size and the fairly young age of the included patients (mean age 44.73 years), the likelihood of finding a sufficient number of these additional findings would be quite low. Additionally, the inclusion criteria were that all patients had MRI confirmed cervical disc herniations that corresponded to the level of clinical signs of radiculopathy found on physical examination. In other words, the MRI findings could explain the clinical findings.

The treatment method was a manual HVLA cervical manipulation performed by 3 chiropractors working in the same office. The treatment can be described as standardized because the senior chiropractor taught the younger two in the specific treatment method used. But the treatment cannot be considered as standardized for all Swiss chiropractors or for chiropractors from other countries, because HVLA cervical manipulation methods can vary between different practitioners.

Follow up information of the outcome measures were collected by telephone calls. There was a certain time frame allocated for every follow-up time-point to reach the patients. If this was not possible the information was not available for statistical analysis. This resulted in fluctuating sample sizes between the different time-points, which means that the compared groups from different time-points did not include the exact same patients.

For the reliability study the relatively low experience level of the examiners can also be taken as a limitation.

Conclusion

This study showed a tendency for a higher proportion of Modic positive patients to report improvement after treatment with high-velocity, low amplitude cervical spinal manipulative therapy compared to Modic negative patients. This was also the case when Modic type I changes were compared to no Modic changes although the sample size for Modic type I patients was very small. This is in contrast to the results of most other studies on this topic to date where Modic positive patients had worse responses to other non-surgical treatments. Further research is needed to confirm these results with a larger sample size and find possible explanations. Additionally, the morphology and axial location of the cervical herniation was not related to treatment outcomes, similar to findings in lumbar disc herniation patients treated with SMT.

The interexaminer reliability for detecting and classifying Modic changes as well as cervical disc herniation location and morphology in MRI studies showed similar results as previously reported in the literature.

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Legends for Figures:

Table 1. Percentage of patients with clinically significant improvement (i.e. 'much better' or 'better' on the 7 point Likert scale) at different time points for patients with and without MC and total number of the different groups at each time point.

	All (%)	N°	MC+ (%)	N°	MC- (%)	N°	MC I (%)	N°	MCII (%)	N°
2 weeks	56.3	32	77.8	9	53.3	30	50.0	2*	83.3	6
1 month	68.3	41	90.9	11	68.4	38	100.0	4*	100.0	5
3 months	86.7	45	100.0	13	85.7	42	100.0	5	100.0	6
6 months	88.4	43	91.7	12	90.2	41	100.0	4*	100.0	6
1 year	100.0	41	100.0	11	100.0	40	100.0	5	100.0	6

All= all patients, N° = total number of patients in the corresponding group, * = insufficient number of patients to perform Chi^2 test, MC = Modic changes, MC+ = patients with MC, MC- = patients without MC

Table 2. Median score comparisons between MC positive and MC negative patients at baseline and all time points regarding NRS neck pain, NRS arm pain and NDI total score.

	MC (Y/N)	N°	Median (Inter-quartile range)	p-value
Baseline NRS neck	Y	13	7.0 (4.0)	0.08
	N	31	5.5 (2.5)	
Baseline NRS arm	Y	13	8.0 (4.75)	0.30
	N	31	6.5 (4.5)	
Baseline NDI total	Y	13	23.0 (15.0)	**0.04***
	N	31	15.0 (11.0)	
2 weeks NRS neck	Y	9	3.0 (1.5)	0.92
	N	22	3.5 (1.88)	
2 weeks NRS arm	Y	9	3.0 (0.75)	0.54
	N	22	5.0 (1.88)	
2 weeks NDI total	Y	9	13.0 (9.0)	0.75
	N	22	13.5 (8.0)	
1 month NRS neck	Y	11	3.0 (0.0)	0.72
	N	29	2.0 (0.75)	
1 month NRS arm	Y	11	0.5 (0.0)	0.21
	N	29	2.0 (1.0)	
1 month NDI total	Y	11	8.0 (4.0)	1.00
	N	29	8.0 (4.0)	
3 month NRS neck	Y	13	1.0 (0.0)	0.94
	N	31	1.0 (0.0)	
3 month NRS arm	Y	13	0.0 (0.0)	0.34
	N	31	1.0 (0.0)	
3 month NDI total	Y	13	5.0 (1.5)	0.48
	N	31	3.75 (2.0)	
6 month NRS neck	Y	12	2.0 (0.25)	0.09
	N	31	1.0 (0.0)	
6 month NRS arm	Y	12	0.25 (0.0)	0.57
	N	31	0.0 (0.0)	
6 month NDI total	Y	12	4.0 (2.4)	0.07
	N	31	2.0 (0.0)	
1 year NRS neck	Y	11	1.0 (0.0)	0.46
	N	29	0.0 (0.0)	
1 year NRS arm	Y	11	0.0 (0.0)	0.81
	N	29	0.0 (0.0)	
1 year NDI total	Y	11	1.10 (0.0)	0.91
	N	29	1.00 (0.0)	

MC = Modic changes, NRS neck = Numerical rating scale for neck pain, NRS arm = Numerical rating scale for arm pain, NDI total = Neck disability index total score, Y = Yes, N = No, N° = patient number, SD = Standard deviation, * = $p < 0.05$.

Table 3. Differences for NRS neck pain, arm pain and NDI total change scores between MC positive and MC negative patients for all time points.

	MC (y/n)	N°	Mean (SD)	t-test statistics
2 weeks NRS neck change	Y	9	2.89 (2.77)	p = 0.20
	N	22	1.66 (2.22)	*t(29) = 1.30, d = .49*
2 weeks NRS arm change	Y	9	3.00 (2.49)	p = 0.30
	N	22	1.77 (3.10)	*t(29) = 1.05. d = .44*
2 weeks NDI change	Y	9	5.56 (3.40)	p = 0.20
	N	22	3.39 (4.38)	*t(29) = 1.32, d = .56*
1 month NRS neck change	Y	11	3.86 (3.56)	p = 0.19
	N	29	2.48 (2.78)	*t(38) = 1.30. d = .44*
1 month NRS arm change	Y	11	4.14 (3.82)	p = 0.75
	N	29	3.79 (2.62)	*t(38) = 0.33. d = .11*
1 month NDI change	Y	11	9.91 (6.70)	p = 0.73
	N	29	6.36 (4.95)	*t(38) = 1.84. d = .61*
3 months NRS neck change	Y	13	4.61 (3.65)	p = 0.22
	N	31	3.24 (2.83)	*t(42) = 1.35. d = .43*
3 months NRS arm change	Y	13	5.31 (3.31)	p = 0.38
	N	31	4.32 (3.41)	*t(42) = 0.88. d = .29*
3 month NDI change	Y	13	15.15 (6.80)	p = 0.20
	N	31	10.87 (6.98)	*t(42) = 1.87. d = .62*
6 months NRS neck change	Y	12	4.00 (2.85)	p = 0.07
	N	31	2.63 (3.24)	*t(41) = .35. d = .12*
6 months NRS arm change	Y	12	4.21 (2.86)	p = 0.45
	N	31	4.94 (2.81)	*t(41) = -.76. d = -.26*
6 month NDI change	Y	12	14.32 (6.71)	p = 0.07
	N	31	12.06 (7.92)	*t(41) = .87. d = .31*
1 year NRS neck change	Y	11	5.36 (2.61)	p = 0.39
	N	29	4.16 (2.79)	*t(38) = 1.25. d = .45*
1 year NRS arm change	Y	11	5.50 (3.69)	p = 0.94
	N	29	5.41 (2.81)	*t(38) = .08. d = .03*
1 year NDI change	Y	11	14.48 (7.21)	p = 0.52
	N	29	12.97 (5.95)	*t(38) = .66. d = .23*

MC = Modic changes, NRS neck/arm change = Numerical rating scale for neck pain/arm pain change score, NDI change = Neck disability index change score, Y = Yes, N = No, N° = Patient number, SD = Standard deviation

Table 4. Differences for NRS neck pain, arm pain and NDI total change scores between MC negative and MC I patients for all time points.

	MC (0/I)	N°	Mean (SD)	t-test statistics
2 weeks NRS neck change	0	22	1.66 (2.22)	p = 0.27
	I	2	3.50 (2.12)	*t(22) = 1.12. d = .85*
2 weeks NRS arm change	0	22	1.77 (3.10)	p = 0.24
	I	2	4.50 (0.71)	*t(22) = 1.22. d = 1.43*
2 weeks NDI change	0	22	3.39 (4.38)	p = 0.40
	I	2	6.50 (2.12)	*t(22) = .98. d = .96*
1 month NRS neck change	0	29	2.48 (2.78)	p = 0.06
	I	4	3.88 (4.77)	*t(33) = .86. d = .37*
1 month NRS arm change	0	29	3.79 (2.62)	p = 0.14
	1	4	5.87 (2.17)	*t(33) = 1.51. d = .78*
1 month NDI change	0	29	6.36 (4.95)	p = 0.44
	I	4	10.00 (6.98)	*t(33) = 1.32. d = .61*

3 months NRS neck change	0 I	31 5	3.24 (2.83) 6.00 (3.74)	$p = 0.12$ *t(36) = 1.94. d = .84*
3 months NRS arm change	0 1	31 5	4.32 (3.41) 7.10 (2.92)	$p = 0.10$ *t(36) = 1.72. d = .88*
3 months NDI change	0 I	31 5	10.87 (9.98) 16.00 (7.71)	$p = 0.34$ *t(36) = 1.51. d = .70*
6 months NRS neck change	0 I	31 4	3.63 (3.24) 5.00 (3.56)	$p = 0.20$ *t(35) = .79. d = .40*
6 months NRS arm change	0 1	31 4	4.94 (2.81) 5.88 (2.39)	$p = 0.53$ *t(35) = .64. d = .36*
6 months NDI change	0 I	31 4	12.06 (7.92) 15.75 (8.50)	$p = 0.14$ *t(35) = .87. d = .45*
1 year NRS neck change	0 I	29 5	4.16 (2.79) 6.30 (2.86)	$p = 0.39$ *t(34) = 1.58. d = .76*
1 year NRS arm change	0 1	29 5	5.41 (2.81) 7.70 (2.68)	$p = 0.10$ *t(34) = 1.69. d = .83*
1 year NDI change	0 I	29 5	12.97 (5.95) 18.40 (6.27)	$p = 0.07$ *t(34) = 1.87. d = .89*

MC = Modic changes, NRS neck/arm change = Numerical rating scale for neck pain/arm pain change score, NDI change = Neck disability index change score, 0 = no Modic changes, I = Modic changes type I, N° = Patient number, SD = Standard deviation, $p < 0.05$

Table 5. Kappa and percentage analysis of interexaminer reliability of the MRI evaluation.

	MC present/absent	MC cat	CDH loc	MC level	CDH level	MC/CDH same	CDH class
Kappa	1.00	0.86	0.42	0.62	0.29	0.82	0.60
%	100	94	53	73	71	93	68

MC cat = Modic changes category (type I, type II), CDH loc = Cervical disc herniation location (central, paramedian, foraminal or extraforaminal), MC level = Spinal level of Modic changes (i.e. C5/6), CDH = Spinal level of Modic changes, MC/CDH same = Modic changes and cervical disc herniation at the same level, CDH class = Cervical disc herniation classification (bulge, protrusion, extrusion, sequester), Kappa = Kappa reliability value; poor (0 – 0.2), fair (0.21 – 0.40), moderate (0.41 – 0.60), substantial (0.61 – 0.80) and almost perfect (0.81 – 1.00)

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